

### **REMARKS**

This application has been carefully reviewed in light of the Office Action dated October 24, 2008. Claims 1-5, and 8-11 remain in this application. Claims 1 and 11 are the independent Claims. Claim 1 has been amended. Claims 10 and 11 are the new Claims. Claims 6 and 7 have been canceled, without prejudice. Support for the amendments is found, inter alia, at Paragraphs [0009], [0011], [0019], [0028], [0039], [0042], [0048] and [0053] of Applicant's published application. It is believed that no new matter is involved in the amendments or arguments presented herein.

Reconsideration and entrance of the amendment in the application are respectfully requested.

#### **Non-Art Based Rejections**

Claims 1-5, 8 and 9 were rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. In response, Claim 1 is amended to address the concern expressed in the Action.

Reconsideration and withdrawal of the above § 112 rejections are respectfully requested.

#### **Art-Based Rejections**

Claims 1, 2, 4, 8 and 9 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Pub. No. 2002/0177855 (Greene); Claims 1-5 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,846,210 (Ogawa) in view of U.S. Patent No. 5,853,418 (Ken).

Applicant respectfully traverses the rejections and submits that the claims herein are patentable in light of the clarifying amendments above and the arguments below.

**The Ogawa et al. Reference**

Ogawa is directed to a medical wire including a conductive guide wire and a meltable joint member 15 (*See, Ogawa; Abstract and Fig. 1*).

**The Greene et al. Reference**

Greene is directed to an embolization device including a plurality of micropellets 12 and polymer members 404 embolizing elements 12 and polymer member 404 provided discontinuously along the length of the embolization device (*See, Greene; Figs. 1 and 41*).

**The Ken Reference**

Ken is directed to an implantable vaso-occlusive device (*See, Ken; Abstract and Fig. 1*).

**The Claims are Patentable Over the Cited References**

The present application is generally directed to an embolus forming in-vivo indwelling coil.

As defined by amended independent Claim 1, an embolus forming in-vivo indwelling device includes a coil separating member and a coil main body having flexibility. A stretch suppressing member is provided on one or both of the inner and outer peripheries of the coil main body and is made of a water-swellaable polymer material for suppressing stretch of the coil main body by swelling with absorbed water. In case that the dry stretch suppressing member is provided on the inner peripheries of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body or in case that the dry stretch suppressing member is provided on the outer periphery of the coil main body, the stretch suppressing member has the clearance between the outer periphery of the coil main body and the inner

periphery of the stretch suppressing member. The stretch suppressing member enters the coil pitches of the coil main body as a result of swelling.

The applied references do not disclose or suggest the features of the present invention as defined by amended independent Claim 1. In particular, the applied references do not disclose or suggest, "in case that the dry stretch suppressing member is provided on the inner peripheries of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body or in case that the dry stretch suppressing member is provided on the outer periphery of the coil main body, the stretch suppressing member has the clearance between the outer periphery of the coil main body and the inner periphery of the stretch suppressing member, and the stretch suppressing member enters the coil pitches of the coil main body as a result of swelling," as required by amended independent Claim 1 of the present invention.

Ogawa is directed to a medical wire including a conductive guide wire and a meltable joint member 15 (*See Ogawa; Abstract and Fig. 1*). Ogawa fails to disclose or suggest a coil separating member and a stretch suppressing member that enters the coil pitches as a result of swelling. Ken does not remedy the deficiencies of Ogawa. Ken is merely cited for teaching for a stretch-resisting member 108 attached to the coil 100 at a first end 104 and second end 106.

Moreover, Greene is directed to an embolization device including a plurality of micropellets 12 (*See Greene; Fig. 1*). In a first embodiment of Greene, micropellets 12 are provided along spaced intervals of filamentous carrier 14 (*See Greene; Figs. 1 and 2 and Paragraphs [0085], [0086], [0094]*). However, even if only one micropellet is provided on a carrier 14, Greene teaches that the carrier 14 includes a distal segment 18 and a proximal segment 22, which are not covered by the micropellet 12 (*See Fig. 1*). Therefore, Greene fails to disclose or suggest a micropellet 12 that extends over the entire region of a coil main body.

Furthermore, Figs. 36 and 39-42 are directed to the method of manufacturing an embolization device. For example, Greene teaches that a hydrogel is first hydrated and then skewered with a filamentous carrier 302. After ejection from the mold, the coaxial polymer member is dehydrated to remove water (*Figs. 24-35 and Paragraphs [0118]-[0128]*). As shown in Figs. 24-35, the carrier 302 is not expanded so as to separate the adjacent turns from each other. Also, the process of forming the embolization device in the mold utilizes hydrated hydrogel and not dry hydrogel. As further shown in Figs. 32-35, the adjacent turns of carrier 302 are not separated from each other. Fig. 36 is directed to a similar process of forming an embolization device where a carrier 402 is inserted into a mold and injected with a hydrated polymer 418. As disclosed in Paragraph [0136], the polymer ejected from the mold of Fig. 36 is the tightly wound devices 400 of Figs. 39 and 41. Greene does not disclose a dry stretch suppressing member that does not occupy the coil pitches of the coil main body and enters the coil as a result of swelling.

In contrast, the present invention requires that in case that the dry stretch suppressing member is provided on the inner peripheries of the coil main body, the stretch suppressing member has a smaller diameter than the coil diameter of the coil main body or in case that the dry stretch suppressing member is provided on the outer periphery of the coil main body, the stretch suppressing member has the clearance between the outer periphery of the coil main body and the inner periphery of the stretch suppressing member. The stretch suppressing member enters the coil pitches of the coil main body as a result of swelling. As disclosed on page 5, line 4 to page 6, line 7 of Applicant's Specification, the invention provides a stretch suppressing member that enters the coil pitches when swelled to create a state in which the adjacent wire turns are substantially connected to each other, but which accordingly does not enter the coil pitches when dry. Since the stretch suppressing member has deformability, the flexibility of the coil main body is not significantly inhibited by the stretch suppressing

member. Therefore, the embolus forming in-vivo indwelling coil can be formed with high flexibility. As a result, the present invention can be securely introduced and recovered with a high degree of safety.

Thus, Ogawa, Ken and Green do not disclose or suggest this feature of the present invention as required by amended independent Claim 1.

Since the applied references fail to disclose, teach or suggest the above features recited in amended independent Claim 1, those references cannot be said to anticipate nor render obvious the invention which is the subject matter of that claim.

Accordingly, amended independent Claim 1 is believed to be in condition for allowance and such allowance is respectfully requested.

Applicant respectfully submits that independent Claim 11 is allowable for at least the same reasons as discussed above with reference to amended independent Claim 1 and such allowance is respectfully requested.

The remaining claims depend either directly or indirectly from amended independent Claim 1 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance and such allowance is respectfully requested.

### **Conclusion**

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los

Appl. No. 10/541,469  
Amdt. Dated January 26, 2009  
Reply to Office Action of October 24, 2008


Attorney Docket No. 81844.0038  
Customer No.: 26021

Angeles, California telephone number (310) 785-4721 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,  
HOGAN & HARTSON L.L.P.

Date: January 26, 2009

By:   
\_\_\_\_\_  
Dariush G. Adli  
Registration No. 51,386  
Attorney for Applicant(s)

1999 Avenue of the Stars  
Suite 1400  
Los Angeles, CA 90067  
Phone: (310) 785-4600  
Fax: (310) 785-4601